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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/311,720	05/14/99	GLENN G	PM254809

HM12/0913
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EXAMINER	
TUNG, M	
ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 09/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Acti n Summary

Application No.	Applicant(s)
09/311,720	Glenn And Alving
Examiner	**Group Art Unit**
Mary B. Tung	1644

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-101* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-101* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Restriction to one of the following inventions is required under *35 U.S.C. § 121:*

   I. Claims 1-44, 47-68, 70-72 and 75-92, are drawn to a method for transcutaneous immunization comprising providing an antigen and an adjuvant, classified in class 424, subclass 184.1.

   II. Claims 45, 46, 69 and 73, 74 are drawn to a method for transcutaneous immunization comprising providing a nucleic acid, classified in class 514, subclass 44.

   III. Claims 93-101, drawn to a formulation, classified in class 424, subclass 184.1.

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I and II and are unique methods. They differ with respect to ingredients, process steps and endpoints to achieve different goals. Therefore, they are patentably distinct each from the other.

4. Groups III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the antigen, can be used in a process to manufacture monoclonal antibodies, for example.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and classifications, and because a non-patent literature and/or sequence search of any or these three distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

6. Should Applicants traverse on the ground that the members of the groups are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the members to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

7. Irrespective of whichever group the Applicant may elect, the Applicant is further required under 35 U.S.C. 121:

8. If Group I is elected, the Applicant is further required to elect a **specific pathogen**: bacterium, virus, fungus, or parasite, as recited in claims 32-36.

9. If Group I is elected, the Applicant is also required to elect a **specific immune response antigen**: autoantigen, tumor antigen, or allergen, as recited in claims 47-54..

10. If Group I is elected, the Applicant is required to elect a **specific adjuvant**: cholera toxin, pertussis toxin, and so forth, as recited in claims 64-68 and 71.

11. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

12. Should Applicants traverse on the ground that the members of the species are not patentable distinct, Applicant should submit evidence or identify such evidence now of record showing the members to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

13. Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added

after the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. The following claim(s) are generic: claims 1-31, 36-40, 44, 55-63, 72 and 75-92.

15. The species are distinct each from the other for the following reasons:

16. A bacterium, virus, fungus, or parasite cause different diseases, that have different etiologies, clinical presentations and treatment modalities.

17. Cholera toxin, pertussis toxin, and so on, have different biochemical characteristics, activities, target cells and would be measured using different reagents.

18. The recited antigens, autoantigen, tumor antigen, or allergen, have different biochemical characteristics, structure and are associated with different disease states.

19. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with *37 C.F.R. § 1.48(b)* if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under *37 C.F.R. § 1.48(b)* and by the fee required under *37 C.F.R. § 1.17(h)*.

Conclusion

21. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

22. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the

status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

Mary B Tung

September 12, 2000
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640